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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,371	08/27/2003	Henryk Borowy-Borowski	61810-5019-US03	3708

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EXAMINER

LANDAU, SHARMILA GOLLAMUDI

ART UNIT	PAPER NUMBER
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1611

MAIL DATE	DELIVERY MODE
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06/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/648,371	Applicant(s) BOROWY-BOROWSKI ET AL.	
	Examiner Sharmila Gollamudi Landau	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/7/08; 4/17/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-18 and 21-23 are pending in this application. Claims 19-20 and 24-27 stand cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/176626.

WO '626 discloses a composition comprising ubiquinone (a terpenoid compound) and a solubilizing agent wherein the lipophilic moiety is selected from sterols, the solubilizing moiety is polyethylene glycol, and the linking agent is sebacic acid (polyoxyethanyl-cholesteryl-sebacate). See page 19-21. The molar ratio of ubiquinone to polyoxyethanyl-cholesteryl-sebacate is about 1:2 to about 1:10 and preferably about 1:3. see page 21, 1st paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/176626 in view of WO 98/03170.

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The disclosure of WO '726 has been set forth above. In particular, WO '726 teaches polyoxyethanyl-cholesteryl-sebacate (PCS) solubilizes ubiquinone (terpenoid).

WO '626 does not specify other lipophilic compounds.

WO '170 teaches lipophilic compounds such as ubiquinone, carotenoids, lutein, lycopene, etc. require solubilizing to enhance bioavailability. See page 4-5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of WO '626 and WO '170 and expect PCS to solubilize other lipophilic compounds. One would have expected PCS to solubilize the instant actives since WO '626 teaches ubiquinone is a lipophilic compound that requires solubilizing with solubilizing agent to increase bioavailability and WO '170 teaches ubiquinone, carotenoids, lutein, and lycopene are lipophilic compounds that require solubilization to increase bioavailability. Further, a skilled artisan would have expected success since ubiquinone, carotenoids, lutein, and lycopene are all terpenoids.

Regarding claim 10, WO '626 teaches the method of solubilizing ubiquinone as claimed. See page 21. It would have been obvious to one of ordinary skill in the art at the time the invention was made to solublize any terpenoid such as astaxanthin, in a similar manner.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/176626 in view of Crooks (4,572,915).

The disclosure of WO '726 has been set forth above. In particular, WO '726 teaches polyoxyethanyl-cholesteryl-sebacate (PCS) solubilizes ubiquinone (terpenoid).

WO '626 does not specify other lipophilic compounds.

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Crooks teaches lipophilic compounds such as fat soluble vitamins, fat soluble drugs, essential fatty acids such as fish oil, carotene, etc, with solubilizing agent to enhance absorption in the digestive system. See column 1, lines 1-15 and column 2, lines 45-65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of WO '626 and Crooks and expect PCS to solubilize other lipophilic compounds. One would have expected PCS to solubilize the instant actives since Crooks teaches fat soluble vitamins, essential fatty acids such as fish oil, and are lipophilic compounds that require solubilization to increase bioavailability. Further, a skilled artisan would have reasonably expected PCS to solubilize any lipophilic compound.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 and 21-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-43 of copending Application No. 11/888332 and claims 1-89 of 12/024936.

The instant application is directed to water-soluble compositions comprising polyoxyethanyl-cholesteryl-sebacate (PCS); polyoxyethanyl-sitosterol-sebacate; polyoxyethanyl-tocopheryl-sebacate and a lipophilic compound. The claimed compounds are terpenes, terpenoids, polyunsaturated fatty acids, tocotrienol, and Coenzyme Q10.

Copending application '332 is also directed to water-soluble compositions comprising polyoxyethanyl-cholesteryl-sebacate (PCS); polyoxyethanyl-sitosterol-sebacate; polyoxyethanyl-tocopheryl-sebacate and a lipophilic compound. The claimed compounds are terpenes, terpenoids, polyunsaturated fatty acids, tocotrienol, and Coenzyme Q10. The copending application's have the same dependent limitations.

Copending application '332 is also directed to water-soluble compositions comprising polyoxyethanyl-cholesteryl-sebacate (PCS); polyoxyethanyl-sitosterol-sebacate; polyoxyethanyl-tocopheryl-sebacate and a lipophilic compound. The claimed compounds are terpenes, terpenoids, polyunsaturated fatty acids, tocotrienol, and Coenzyme Q10. The copending application's have the same dependent limitations.

Therefore, both applications are directed to overlapping subject matter.

This is a provisional obviousness-type double patenting rejection.

Allowable Subject Matter

Claims 8-9, 12-18, and 21-23 are free of prior art rejections (excluding the double patenting rejection). The prior art of record discloses tocopherol polyethylene glycol carboxylic

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acid esters, specifically tocopherol polyethylene glycol succinate (TPGS), as a solubilizing agent for lipophilic active agents. However, applicant's specification is directed to solubilizing agent(s) not disclosed by the prior art. Further, the present agents are an improvement over the prior art in terms of the solubilizing agent's low toxicity as compared to the prior art's TPGS. See Figure 1 and Example 14.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is (571) 272-0614. The examiner can normally be reached on Monday- Friday (8:30-6).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharmila Gollamudi Landau/
Primary Examiner, Art Unit 1611

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